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HUMAN RIGHTS AND SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS

Human rights and bioethics

Report of the Secretary-General

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Introduction

1. At its forty-ninth session, the Commission on Human Rights, in its resolution 1993/91 of 10 March 1993, aware of the rapid development of the life sciences and the dangers that certain practices may pose to the integrity and dignity of the individual and seeking to ensure that scientific progress benefits individuals and develops in a manner respectful of fundamental human rights, invited Governments, the specialized agencies and other organizations of the United Nations system, in particular the United Nations Educational, Scientific and Cultural Organization and the World Health Organization, and other intergovernmental, particularly regional, organizations and non-governmental organizations to inform the Secretary-General of activities being carried out to ensure that the life sciences develop in a manner respectful of human rights.

2. The Commission further invited States to inform the Secretary-General of legislative or other measures taken to this effect, including the possible establishment of national consultative bodies, with a view to promoting exchanges of experience between such institutions.

3. The Commission also requested the Secretary-General to prepare a report on the basis of these contributions for consideration by the Commission at its fifty-first session.

4. Pursuant to that resolution, the Secretary-General, by a communication dated 8 November 1993, invited States and interested intergovernmental and non-governmental organizations to submit their contributions to the Centre for Human Rights by 1 April 1994.

5. By 30 October 1994, replies had been received from the Governments of Belarus, Canada, Cyprus, Denmark, Finland, Germany, the Holy See, Monaco, Namibia, Norway, Paraguay, Portugal, the Russian Federation, Spain, Sweden and Ukraine.

6. The United Nations Educational, Scientific and Cultural Organization and the World Health Organization also sent replies.

7. The Council of Europe sent an information paper on the work presently being carried out by the Council in this field.

8. The Council for International Organizations of Medical Sciences also sent a reply.

9. The present report is submitted to the Commission in pursuance of resolution 1993/91.

I. BACKGROUND: MEASURES TAKEN BY THE UNITED NATIONS

10. The interest of the United Nations in bioethics can be dated from the International Conference on Human Rights held at Tehran in 1968. This interest may be derived from the general concept of the impact of recent scientific and technological developments on human rights. In paragraph 18 of the Proclamation of Tehran, the Conference expressed the view that "while recent scientific discoveries and technological advances have opened vast prospects for economic, social and cultural progress, such developments may nevertheless endanger the rights and freedoms of individuals and will require continuing attention". The Conference, in resolution XI, considered the need for "thorough and continuous interdisciplinary studies at both the national and the international level" and recommended to the organizations of the United Nations family that they undertake studies of the problems with regard to, among others, protection of the human personality and its physical and intellectual integrity in view of the progress in biology, medicine and biochemistry.

11. Later in 1968, the General Assembly adopted resolution 2450 (XXIII) of 19 December 1968, in which the Assembly, sharing the concern expressed by the Conference and endorsing the idea that the problems cited by the Conference required thorough and continuous interdisciplinary studies, which might serve as a basis for drawing up appropriate standards to protect human rights and fundamental freedoms, invited the Secretary-General to undertake a study of the problems in connection with human rights arising from developments in science and technology, in particular from the standpoints recommended by the Conference.

12. In compliance with this request, the report on the protection of human personality and its physical and intellectual integrity, in the light of advances in biology, medicine and biochemistry (E/CN.4/1172 and Add.1-3 and Corr.1) was prepared. The report dealt with the beneficial use of artificial insemination, psychotropic drugs, procedures of pre-natal diagnosis and chemicals introduced into food production, processing, packaging and storage.

13. The human rights aspects of advances in biology, medicine and biochemistry were examined briefly. In particular, it was pointed out that scientific advances in the fields of biology, medicine and biochemistry have brought many benefits to human beings through improved health and medical care, the extension of life expectancy and reduction in infant mortality, and the alleviation of many of mankind's diseases and afflictions. At the same time, it had become increasingly recognized that the human personality may need to be protected, both physically and intellectually, for some of these advances that may pose threats to human integrity.

14. The outcome of this and other studies demonstrated that the results of science and technology, in many cases, are transformed into technological procedures, into new and more sophisticated tools, into equipment and machines. However, technologies are not an end in themselves. The aim of all scientific and technological activity is man and his life.

15. The Commission on Human Rights, at its thirty-third session in 1977, considered a number of reports on various aspects of human rights and

scientific and technological developments which it had been unable to examine at earlier sessions, including the report on the protection of the human personality and its physical and intellectual integrity in the light of advances in biology, medicine, and biochemistry.

16. The General Assembly, in its resolution 3268 (XXIX) of 10 December 1974, requested the Commission to draw up a programme of work, with a view to undertaking in particular the formulation of standards which would appear to be sufficiently analysed.

17. On 11 March 1977, the Commission on Human Rights, in resolution 10 A (XXXIII), requested the Sub-Commission to study, with a view to formulating guidelines, if possible, the question of the protection of those detained on the grounds of mental ill-health against treatment that might adversely affect the human personality and its physical and intellectual integrity. However, it was not until 1980 that the Sub-Commission appointed a Special Rapporteur to prepare a study on the protection of persons detained on the grounds of mental ill-health.

18. Mrs. Erica-Irene Daes, the Special Rapporteur, submitted her final report on the subject to the Sub-Commission in 1982. The Special Rapporteur also submitted a draft body of principles, guidelines and guarantees for the protection of those persons (E/CN.4/Sub.2/1983/17/Rev.1).

19. Pursuant to the request made by the General Assembly in a number of resolutions, in particular its resolution 45/92 of 14 December 1990, the Sub-Commission initiated and the Commission elaborated a body of principles for the protection of persons with mental illness and for the improvement of mental health care. By its resolution 46/119 of 17 December 1991, the General Assembly adopted the Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care.

20. Principle 11.15 states, inter alia, that "clinical trials and experimental treatment shall never be carried out on any patient without informed consent, except that a patient who is unable to give informed consent may be admitted to a clinical trial or given experimental treatment, but only with the approval of a competent, independent review body specifically constituted for this purpose". Principle 11.12 states that "sterilization shall never be carried out as a treatment for mental illness".

21. The United Nations has also laid down a number of other standards relating to human rights and bioethics. Some of them are legally binding rules while others represent general principles of international law. Potential uses of recently acquired knowledge about human biology benefit or threaten several of the rights embodied in the International Covenant on Civil and Political Rights, including the right to life (art. 6), the right not to be subjected to medical or scientific experimentation (art. 7), the right to security of the person (art. 9) and the right not to be subjected to arbitrary or unlawful interference with privacy, family, home or correspondence, (art. 17).

22. Therefore, at least four substantive provisions constituting legally binding rules of international law bear in varying degrees on issues arising

from the rapid advance in knowledge and technology affecting the process of life creation. But, as has been suggested, more is at stake than those four rights or, indeed, all the rights codified in the Covenant and other human rights instruments. The very idea of human rights arguably rests on a certain conception of what it means to be human, on a reverence for life and for autonomy, all of which could conceivably be undermined if the production, maintenance, manipulation and termination of embryos became commonplace, and particularly if this activity were carried on to a considerable extent for profit. Parallel expansion of the extant semi-clandestine market in body parts will aggravate that risk. One way of putting the issue is whether the idea of human rights will continue to enjoy powerful support in an environment characterized by the "commodification of the body". 1/

23. Reference can also be made to some principles proclaimed by the General Assembly and relevant to the subject considered here. Many articles of the Universal Declaration of Human Rights are of primary importance in this area. According to the 1975 Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind (General Assembly resolution 3384 (XXX) of 10 November 1975), according to which all States shall, inter alia, take appropriate measures, including legislative measures, to prevent the use of scientific and technological developments to limit or interfere with the enjoyment of human rights and fundamental freedoms.

24. One should recall article II (d) of the Convention on the Prevention and Punishment of the Crime of Genocide (1948) which condemns as a crime under international law imposing measures intended to prevent birth within a (national, ethnic, racial or religious) group with intent to destroy such a group in whole or in part.

25. The General Assembly adopted in 1982 the Principles of Medical Ethics relevant to the Role of Health Personnel, particularly Physicians, in the Protection of Prisoners and Detainees against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment. WHO points out that the "Background Note" to the Principles affirmed that "(a) detailed code of medical ethics applicable in all contexts and in all times is ... unthinkable. There are nevertheless general principles of medical ethics of universal applicability". It is stated further that the "six Principles of Medical Ethics provide clear guidance to the medical and allied professions of the world and weighty moral support for resisting any pressures to use their knowledge and skills for other than beneficent ends".

26. The World Health Organization stated as follows:

> "There are no references to ethics in general or medical ethics in particular in WHO's Constitution, adopted by the International Health Conference held in New York from 19 June to 22 July 1946. Nor, it must be conceded, have ethical issues occupied a prominent position in debates within WHO's governing bodies, the Executive Board and the World Health Assembly, or in resolutions adopted by either of these bodies. However, the Constitution does include an Article 63 under which each member State is required to communicate promptly to the Organization important laws

and regulations pertaining to health that have been published in the particular State. It is on the basis of that mandate that WHO has endeavoured to systematically compile, process and disseminate information on all major international and national legislative and related developments in the field of bioethics. The primary vehicle for disseminating this information is the WHO quarterly journal, the International Digest of Health Legislation. Each issue of the Digest includes a section devoted to 'Ethical issues and professional responsibility', as well as other sections devoted to 'Human reproduction and population policies' and 'Death and related issues'."

27. A number of United Nations reports and studies elucidated the impact of scientific and technological developments on the rights proclaimed in the Universal Declaration of Human Rights and embodied in the International Covenants on Human Rights. They included an examination of the impact, both beneficial and harmful, of scientific and technological developments upon the rights laid down in the International Bill of Human Rights and other relevant instruments. 2/ It was felt that principles and legal rules laid down in the International Bill of Human Rights should be accorded special importance in the application of scientific and technological progress.

28. As to recent developments, the World Conference on Human Rights, held in Vienna in June 1993, emphasized that everyone had the right to enjoy the benefits of scientific progress and its applications. In particular, it noted that certain advances, notably in the biomedical and life sciences as well as in information technology, may have potentially adverse consequences for the integrity, dignity and human rights of the individual, and called for international cooperation to ensure that human rights and dignity are fully respected in this area of universal concern.

29. The World Conference on Human Rights also recognized that illicit dumping of toxic and dangerous substances and waste potentially constituted a serious threat to the human rights, life and health of everyone. Consequently, the Conference called on all States to adopt and vigorously implement existing conventions relating to the dumping of toxic and dangerous products and waste and to cooperate in the prevention of illicit dumping.

30. In addition, the Conference urged that special attention should be given to ensure universal respect for, and effective implementation of the Principles of Medical Ethics.

31. The Vienna Declaration and Programme of Action contains provisions aimed at strengthening of national and international mechanisms and programmes for the promotion and protection of the rights of women, children, migrant workers and persons with disabilities. Issues raised in this context include the elimination of the harmful effects of certain traditional or customary practices, a women's right to accessible and adequate health care and the widest range of family planning services, the sale of organs, AIDS, female infanticide, sexual abuse and other issues relating to human rights and medical ethics.

II. LEGISLATIVE AND OTHER MEASURES TAKEN AT NATIONAL AND REGIONAL LEVELS TO ENSURE THAT THE LIFE SCIENCES DEVELOP IN A MANNER RESPECTFUL OF HUMAN RIGHTS

A. General observations

32. The Governments and organizations which sent replies to the communication from the Secretary-General recognized the need to ensure that the life sciences develop in a manner respectful of human rights. There is also a unanimity of opinion that whereas scientific and technological developments are a motive force in human advancement, the choice of values, objectives and goals is not inherent in the nature of science and technology.

33. The Government of Norway considers that the Government's main objective is to make use of modern medical expertise and technology in the best interests of mankind within the ethical boundaries laid down by society. The use to which the different forms of modern biotechnological treatment will be put, and the research that developing this will entail, must be viewed separately. This will allow a distinction to be drawn between that which is considered ethically defensible, and that which must be abandoned on the grounds that it is questionable and undesirable. Such a distinction must be drawn in the light of developments in the field of medicine. This will not be easy and it will not be possible to draw a distinction once and for all, as research will continually lead to change. Developments will evoke difficult ethical questions for which there will be no simple answers. The need to practise must be weighed up against the possibilities created by development.

34. Referring to paragraph 18 of the Proclamation of Tehran, the Holy See stated that economic and social aspects of the fundamental rights of an individual were not alien to the field of relations between life sciences and human rights. Therefore, biogenetic research and experimentation encompassed vast areas of social life, thus demonstrating that enjoyment of some rights depended on their socio-economic contents.

35. According to a concept put forward by the Government of Paraguay, bioethics is the systematic study of human behaviour in the field of life sciences and health care, from the standpoint of moral values and principles.

36. The Council for International Organizations of Medical Sciences (CIOMS) pointed out that the remarkable progress of biomedical sciences and biotechnology, and their application in medical practice, were confronting our societies with new ethical dilemmas, extending from traditional medical ethics to the new fields of bioethics and health-policy ethics. In its opinion, unlike traditional ethics, with its medical model, bioethics is interdisciplinary, reflecting the reality that medical choices can no longer be made purely on the basis of medical science. Bioethics differs from medical ethics also in that it incorporates a social dimension, being concerned with justice and rights, honesty and respect for human dignity, autonomy of the individual and respect for communities. Health policy ethics may be seen as an aspect of bioethics concerned particularly with the organization, financing and delivery of health care.

B. Legislative, administrative and other measures aimed at protecting human rights in the bioethical context

1. Medical treatment

37. In Canada, the Canada Health Act adopted by the federal authorities contributes to ensuring that the right to the highest attainable standard of health is respected. The Act establishes the basic criteria for eligibility for federal funding of provincial territorial health systems: public administration, comprehensiveness regarding health care services that are covered, universality regarding persons entitled to coverage, portability from one province to another, and accessibility of health care services on a uniform and reasonable basis.

38. The Government of Finland states: "Provisions on the most important principles in the care and treatment of patients are included in the Act on the Status and Rights of Patients. The Act includes provisions on a patient's right to good care and treatment, access to care, self-determination and right to be informed, the status of a minor patient, making and keeping of patient files, secrecy of the information contained in patient files, patient ombudsman and complaints. Provisions on care irrespective of the patient's will are included in the Act on special care for the mentally retarded, Act on welfare for alcoholics and drug addicts, Communicable Diseases Act and Mental Health Act."

39. A provision of the Criminal Code of Canada relevant in the biomedical context is section 14 in accordance with which no one may consent to have death inflicted on himself (or herself).

40. In regard to consent to medical treatment, section 11 of the Civil Code of Quebec provides that no one may cause a person to undergo medical care of any nature, whether for examination, specimen taking, removal of tissue, treatment, or any other act, except with his or her consent. Section 12 requires that a person designated to give consent on behalf of another person act in the sole interest of that person, taking into account where possible his or her wishes. Section 13 provides for an exception to the consent requirement in case of emergency, section 14 concerns a minor (the consent of parent or tutor required) and section 15 concerns persons of full age incapable of giving consent to care required by his or her health. Pursuant to section 14 of the Civil Code of Quebec, a person of 14 years of age or older may consent to treatment. In the other provinces and territories consent rules are for the most part established by the common law.

41. As far as case law is concerned, the Supreme Court of Canada has decided a number of cases based on the provisions of the Canadian Charter of Rights and Freedoms and relevant in the biomedical context. For example, on the issue of consent to medical treatment or research the Court concluded, in R. v. Dyment, that section 8 (unreasonable search and seizure) of the Charter was violated when a blood sample which had been taken from an unconscious patient for medical purposes was then transmitted to the police without the consent of the patient. In R. v. Dersch, the Supreme Court of Canada held that section 8 of the Charter

provides certain protection to the right to privacy, and that it was violated when the police obtained information about the results of a blood sample from a hospital without the patient's consent. The Court noted that the hospital was not itself subject to the Charter, as it was not part of Government.

42. With reference to common law, the Canadian Government related that in Reibl v. Hughes, the Supreme Court of Canada held that the test for informed consent in a negligence action arising in the context of medical practice was whether the physician had revealed to the patient all risks that would be material to him or her in determining whether to undergo the treatment in question. More recently, in Ciarlariello v. Schacter, the Supreme Court of Canada stated that where a patient withdraws consent during a medical procedure, the doctors must halt the procedure unless it would be life threatening or pose immediate and serious health problems to the patient to do so, or unless the patient, after receiving all material information - for example, regarding any significant change in risks that had become apparent during the procedure - agrees after all to continue it.

43. In Norberg v. Wynrib, the Supreme Court of Canada held that the defence of consent to an allegation of the tort of battery was not available where "consent" was given by a woman dependent on drugs to a sexual relationship with a doctor in order to obtain drugs. The Court stated that there was a marked inequality in bargaining power between the doctor and the patient in these circumstances, and exploitation of it by the doctor.

44. With respect to civil law, the Canadian Government pointed out that in Nancy B. v. Hôtel Dieu de Québec, the court held that a woman with a serious neurological disorder had the right to decline medical treatment in the form of continued use of a respirator, even though death would result from the cessation of treatment. The Court stated that the right of the individual to decline treatment is almost absolute, subject only to a limitation regarding the life and health of others.

45. In Weiss v. Solomon, the Quebec Superior Court was called upon to consider the implications of Quebec legislation relating to informed consent for research in the context of a person with a heart condition who died of a heart attack upon receiving an experimental treatment involving eye drops. The consent form stated that "some patients may develop a minor allergic reaction to this injection, but the majority have no side effects". In fact there was an established risk for persons with heart conditions, and there had been no pre-screening procedure. The Court concluded that, in non-therapeutic research, there was a duty to inform the subjects of all known risks, however slight, above all where they involve grave consequences. The Court also relied on the lack of a screening procedure in place to find the hospital liable.

46. The draft Convention on Bioethics prepared by the Council of Europe aims at defining general principles and rules to protect the human being with regard to the application of biology and medicine. These draft principles may be divided into four categories. The first one relating to subjects of consensus includes, among others, the following provisions:

"It is widely accepted that:

- no intervention may be carried out without the free and informed consent of the person undergoing it;

- national law shall provide for particular conditions for the protection of incapacitated persons (minors, legally incapacitated adults, de facto incapacitated adults);

- in emergency situations an intervention may be carried out on an individual without the appropriate consent ..."

47. The Commonwealth Medical Association (CMA) reported that, in July 1993, a working group, set up as part of CMA's project on the role of medical ethics in the protection of human rights, prepared guiding principles on medical ethics. Although the principles and commentaries upon them were prepared with the conditions of medical practice in developing countries in mind, they do in fact apply with equal force to medical practice in industrialized countries. But they do not cover ethical and human rights aspects of medical practice that are not yet causing problems in developing countries, e.g. assisted conception, egg donation, telemetric medicine, etc.

48. Principle 3 states that "Treatment and other forms of medical intervention to patients who have the capacity to consent should not be undertaken without their full, free and informed consent".

49. In the commentary to this principle, it is pointed out, in particular, that "patients must always be given sufficient information to enable them to decide whether or not to accept treatment, including the relevant risks of the proposed treatment as well as its expected benefits. Wherever possible available alternative treatments should be offered if the patient objects. A change of mind by the patient at any stage of treatment must always be respected. Physicians should be careful not to exert undue pressure on patients to accept treatment, and should refrain from adopting diagnostic or therapeutic procedures that have not been endorsed by a contemporary competent medical authority. They should take care not to associate themselves with unacceptably coercive health policies such as may have been introduced for population management reasons ...".

50. With respect to confidentiality of medical records, the Canadian Government stated that provincial and territorial legislation protected them. For example, in Ontario, the Mental Health Act provides for the confidentiality of records in mental health facilities, the Freedom of Information and Protection of Privacy Act for ministry and agency records, the Public Hospital Act for public hospital records, and the Child and Family Services Act for records in children's mental health centres, aid societies, group homes, etc.

51. Principle 4 of the guiding principles prepared by the CMA provides that "information obtained in the physician/patient relationship must be regarded as strictly confidential".

52. In the commentary to this principle, it is stated:

> "Physicians must be aware of all relevant aspects of the patient's personal and family medical history in order to give safe and effective treatment. This will often include sensitive information that is unlikely to be disclosed by the patient unless confidentiality is assured. When seeking the patient's consent to disclosure of confidential information, the physician must ensure that the patient understands the reasons for disclosure and its likely consequences. Apart from situations where disclosure is required by law, such as the notification of infectious diseases, there must always be the most compelling reasons before a physician discloses confidential information without the consent of the patient, e.g. an immediate and serious threat to the life or health of other persons. In such cases the physician must notify the patient of the intention to divulge the information when it is possible to do so."

53. Provincial and territorial Governments of Canada are responsible for regulating the health care professions. For the most part regulation of medical practice is delegated to the College of Physicians and Surgeons of each jurisdiction. For example, in Alberta, the Medical Profession Act establishes the College of Physicians and Surgeons as the authority for disciplining its members. The College has not established its own standards of practice, but rather has adopted the Code of Ethics of the Canadian Medical Association, reserving the right to make changes to the Code. In Quebec there is a Code of Ethics for Physicians enacted pursuant to the Medical Act.

54. Section 216 of the Criminal Code of Canada provides that everyone undertaking the administration of medical treatment has a duty to have and use reasonable knowledge, skill and care in administering such treatment. In accordance with section 219, anyone who in doing something, or omitting to do something it is his or her duty to do, shows wanton or reckless disregard for the lives or safety of other persons is criminally negligent, and section 241 states that it is a criminal offence to advise, encourage or aid another person to commit suicide.

55. Principle 5 of the CMA's guiding principles includes the following provision relating to physicians' competence to practice:

> "Physicians in active practice must maintain competence to practise at all times and must ensure that they never expose patients to unnecessary risks."

56. In the commentary to this principle, it is stated:

> "Physicians must take steps to ensure that they keep up-to-date with relevant developments in their fields of practice, and remain competent to provide patients with reliable advice about measures necessary to promote their good health. Patients must not be subjected to risk of avoidable harm from unnecessary or outdated procedures, nor must they be placed at risk as a result of the physician's own health status, e.g. dependence on alcohol or other drugs. Physicians must be able to

recognise clinical situations in which their own professional skills and experience are inadequate and must be willing to refer patients to such suitably qualified and experienced colleagues as may be available."

57. The Government of Norway considered that a State should ensure that persons with disabilities are provided with the same level of medical care within the same system as other members of society. It stated that the Government's primary objective for work with disabled people was to ensure maximum participation and equality. This objective was presented in the Government's plan for action for the disabled.

58. In the view of the CMA, medical care should be provided for all disadvantaged and vulnerable groups. In which category it included women, children, the girl child, adolescent girls, the elderly, refugees, asylum-seekers, minority ethnic groups and indigenous peoples.

59. In this respect, Principle 7 of the CMA's guiding principles states as follows:

"The obligation of a physician to provide medical care for disadvantaged and vulnerable groups must be upheld. Physicians should endeavour to identify the causes of ill health in such groups and should draw attention to the need to alleviate them."

60. The commentary to this principle states:

"All sick or disabled persons are vulnerable in so far as they are likely to be unduly susceptible to suggestions which offer them relief from pain and suffering and a cure of their condition. Physicians must constantly bear this in mind and be careful not to take unreasonable advantage of it. Physicians must also be aware of the special needs of those members of the community who are deprived of adequate access to health care or who have difficulty in making their requirements known."

61. With respect to the role of health care personnel, particularly physicians, attending prisoners and detainees, the Government of Canada pointed out that the Corrections and Conditional Release Act, the regulations enacted thereunder and the Directives of the Commissioner of Corrections governed matters relating to the treatment, health care and living conditions of inmates of federal penitentiaries.

62. Section 69 of the Corrections and Conditional Release Act of Canada provides that no person shall administer, instigate, consent to or acquiesce in any cruel, inhumane or degrading punishment or treatment of inmates. Section 9 of Commissioner's Directive No. 800 relates to the participation of medical personnel in interrogations, and provides that medication shall be provided to inmates only when clinically indicated, and not for restraint or security purposes. Section 89 of the Act prohibits the Correctional Service of Canada from directing force-feeding of an inmate who had the capacity to understand the consequences of fasting at the time the decision to fast was made.

63. With respect to medical attendance upon persons held in detention or imprisonment, Principle 8 of the CMA's guiding principles contains the following provision:

> "Attendance by physicians on persons held in detention must always be conducted in the best interests of their health."

64. In the commentary to this principle, it is stated, in particular, the following:

> "Physicians attending prisoners should take all possible steps to preserve the dignity of detainees, e.g. by insisting wherever possible that medical examinations are carried out in private, that the medical ethical requirements of consent and confidentiality are respected, and that treatment is carried out in a humane manner. They should ensure compliance with United Nations human rights instruments relevant to the care of prisoners and other detainees, particularly those concerned with juvenile detainees."

2. Medical research involving human beings and experiments on human subjects

65. There have been attempts at the international, regional and national levels to control human experimentation and to protect the human personality from the dangers related to it which have led to the elaboration of professional codes of ethics to guide medical research. The first of these was the Nürnberg Code of 19 August 1947, a set of 10 principles relating to medical experiments laid down by the United States Military Tribunal. This code was followed by the Declaration of Geneva, the International Code of Medical Ethics and the Declaration of Helsinki, adopted by the World Medical Association in September 1945, and revised in October 1949, June 1969 and September 1989 respectively.

66. As has been pointed out, the Declaration of Helsinki distinguished between clinical research combined with professional care, on the one hand, and non-therapeutic research, on the other. Some basic principles relate to both. Thus, in both cases, research should be based on laboratory and animal experiments and conducted only by scientifically qualified persons and under the supervision of a qualified medical person. The objective should be in proportion to the inherent risk to the subject, which should be carefully assessed. Special caution should be exercised when the personality of the subject is liable to be altered by drugs or experimental procedures. 3/

67. With regard to non-therapeutic clinical research, the Declaration of Helsinki specifies that, as a rule, consent should be obtained in writing after the subject has been fully informed of the nature, the purpose and the risk of the clinical research. It is stressed that the subject of clinical research should be in such a mental, physical and legal state as to be able to exercise his power of choice and, at any time during the course of the research, should be free to withdraw permission for research to be continued.

68. Article 7 of the International Covenant on Civil and Political Rights which prohibits, in the first place, torture or cruel, inhuman or degrading

treatment or punishment, extends the prohibition to medical or scientific experimentation without the free consent of the person concerned. In its General Comment 7 on article 7 of the International Covenant on Civil and Political Rights, the Human Rights Committee noted that the reports of States parties had generally given little or no information on this point. It took the view that at least in countries where science and medicine are highly developed and even for peoples and areas outside their borders if affected by their experiments, more attention should be given to the possible need and means to ensure the observance of this provision. Special protection in regard to such experiments was considered necessary in the case of persons not capable of giving their consent.

69. Some Governments reported that their State's jurisdictions had legislated on the subject. For instance, Denmark's Law N 503 of 24 June 1992 entitled "Law on a scientific ethical committee and the handling of biomedical research projects", "intends to lay down the legal framework for the scientific ethical evaluation of biomedical research projects" (chap. 1, para. 1).

70. Paragraphs 6 and 7 of chapter 2 entitled "Registration and permission" specifies the following:

> "Section 6, Subsection 1. Every biomedical research project which includes research on: (1) live-born human subjects, (2) human germ cells to be applied in fertilization, human fertilized eggs, embryos and foetuses, (3) tissues, cells or genetic material from human subjects, foetuses and the like and (4) deceased, has to be notified to the regional committee within the area where the person responsible for the project works ...
>
> Subsection 3. The Central Committee can lay down rules for the practical organization of scientific ethical analyses of projects, that are carried out in more than one research institution (multi-centre trials).
>
> Section 7. Projects, comprehended by section 6, must not be initiated until they have been subject to a scientific ethical evaluation and a permission to start has been given by the regional committee, cf. section 14. The regional scientific ethical committee and the Central Committee can demand the project to be changed, and besides give advice and guidance concerning the project plan ..."

71. In accordance with Act N 353 of 3 June 1987, in Denmark the following experiments shall be prohibited:

> "(1) Experiments, the object of which are to enable the production of genetically identical human beings;
>
> (2) Experiments, the object of which is to enable the production of human individuals by fusion of genetically different embryos or parts of embryos before they implant in the uterus (pre-embryos);
>
> (3) Experiments, the object of which is to enable the production of living human individuals who are hybrids with a genetic constitution including elements from other species."

72. The Government of Germany states:

> "Alongside the Protection of Embryos Act, sections 40 and 41 of the Drug Law (Arzneimittelgesetz) contain general and special preconditions necessary to ensure the protection of human beings in the event of clinical trials. These regulations are rendered more effective by means of uniform principles laid down in section 5 of the General Administrative Regulation on the Implementation of the Drug Law in the version of 7 December 1990 (Federal Gazette, p. 6,660). According to these provisions, the competent authority supervises compliance with the regulations taking into account the Principles for the Proper Conduct of Clinical Drug Trials of 9 December 1987 (Federal Gazette, p. 16,617)."

73. The Government pointed out that according to these principles, the ethical and legal prerequisites shall be examined before commencing clinical trials and an independent and competent Ethics Commission shall be heard. These principles provided, in particular, that the clinical trial of a drug could only be conducted if the person on whom it is to be tested gave his or her consent after having been informed by a physician about the nature, significance and implications of the clinical trial and if the person on whom the trial was to be performed was not in the custody of an institution by virtue of a judicial order or official directive. The test person may withdraw his or her consent at any time. Specific regulations shall be observed in conducting clinical trials with minors. For the compilation and documentation of the findings regarding individual persons, a test form shall be used and shall include questions to ascertain whether the test person is pregnant.

74. The Governments of Belarus, the Russian Federation and Ukraine stated that in their States clinical and medico-biological research and experiments on human beings for therapeutic or scientific purposes may be carried out in medical institutions by qualified specialists and practising physicians only with the written consent of the person to be subjected to the research or experiment who, being of age, has been informed of their purpose, expected results and possible consequences for his health. Clinical and medico-biological research and experiments may be carried out on a human being if the scientific justification for them has been confirmed. Clinical and medico-biological research and experiments shall be terminated at the request of the person subjected to the research or in the event of a threat arising to his life or health.

75. The Government of Spain stated that for carrying out clinical and other medical experiments authorization from the Ethical Committee on Clinical Research and the Director-General of pharmaceutical and health products should be obtained.

76. Other States reported that they did not have any legislation expressly and specifically regulating medical research involving human beings. There are, however, a number of policy guidelines in place. For example, in Canada, the Guidelines on Research Involving Human Subjects, 1987, of the Medical Research Council apply to research projects receiving funding from the Medical Research Council (estimated to be about 25 per cent of medical research in Canada). The Guidelines cover such matters as informed and voluntary consent,

research on mentally incompetent persons, research involving risk, confidentiality of information obtained during research and the role of research ethics boards. In regard to research on children, the Guidelines indicate that in certain circumstances, depending on their actual capacities, children may consent to participate in research. In other circumstances, consent of the legal guardian will need to be supplemented by the input of others, such as institutional experts and the child.

77. The Medical Research Council had also adopted Guidelines for Research on Somatic Cell Gene Therapy in Humans, 1990, which dealt with such human rights issues as informed consent, consent with special populations (research on children and research involving human foetuses), evaluation of risk and benefit, confidentiality and ethical and scientific review. The issue is also discussed whether somatic gene therapy should be classified as therapy or as research (with the attendant consequences of stricter supervision).

78. In Canada, regulations enacted pursuant to the Food and Drugs Act require that new drugs be approved by the Minister of Health. Manufacturers are required to file a detailed protocol on the clinical testing of a new drug for the approval of the Drugs Directorate at Health Canada, as well as the results of investigations to support the clinical use of the drug. The Drugs Directorate has developed Guidelines on the Conduct of Clinical Investigations, 1989, which include procedures for the protection of subjects regarding such matters as informed consent, removal of a subject from a trial because of adverse events, and supervision of the trial by an independent review committee.

79. With respect to provincial or territorial legislation, the Government of Canada pointed out that section 20 of the Civil Code of Quebec provided that a person of full age who was capable of giving consent might undergo an experiment, provided the risk assumed was not disproportionate to the expected benefit. Section 21 sets out the limited circumstances in which a minor or adult lacking capacity to consent may be submitted to an experiment, including the approval of the court regarding research on one person alone, and of an ethics committee regarding research on a group of persons.

80. The Government of Finland stated that, in 1986, the National Board of Health gave instructions on arranging research, experiments and development in health care centres and hospitals. These instructions are still observed as recommendations. According to section 86 of the Medicines Act, clinical trials of medicines mean experiments on humans in order to assess the effects of the medicines on humans and their absorption, distribution, metabolism or excretion in the system of a human. By virtue of section 87 of the Medicines Act, a preliminary notification shall be submitted to the National Agency for Medicines of a clinical trial of medicines. The National Agency for Medicines is responsible for the supervision of clinical trials of medicines and for issuing more detailed regulations on them.

81. In its reply, CIOMS pointed out that the scope and methods of epidemiological research, with its continually expanding potential for the collection, storage and use of data on individuals and communities, and with some inevitable tension between the rights and freedoms of the individual and the needs of society, had led to expressions of societal concern about the

risks of abuse and to a demand for the consideration of the ethical issues involved. The need for special ethical guidelines for epidemiological studies has been accentuated by the HIV/AIDS epidemic and the commencement of clinical trials on candidate HIV vaccines and treatment drugs, involving large numbers of research subjects in many parts of the world.

82. The International Guidelines for Ethical Review of Epidemiological Studies were endorsed, in 1991, by the WHO Global Advisory Committee on Health Research and the Executive Committee of CIOMS. The text consists of a statement of general ethical principles, a preamble and 15 guidelines, with an introduction, and a brief account of earlier ethical declarations and guidelines. Each guideline is followed by a commentary. The guidelines reflect the paramount ethical concern for vigilance in protecting the rights and welfare of research subjects and of vulnerable individuals or groups being considered as prospective subjects. The guidelines are designed to be of use, particularly to developing countries, in defining national policies on the ethics of biomedical research, applying ethical standards in local circumstances, and establishing or redefining adequate mechanisms for ethical review of research involving human subjects.

83. The Council of Europe, while preparing the draft Convention on Bioethics, also decided to elaborate some protocols to it. The draft protocol on medical research aims at regulating research on individuals in order to allow only ethically and scientifically sound research to be carried out. This should limit the risks incurred by the persons undergoing the research. In order to fulfil this purpose, the protocol provides for a certain number of conditions such as, inter alia, the existence of a scientific plan and its approval by an ethics committee, the consent of the person undergoing the research or his/her representative where appropriate, limits on the possibility to carry out research on more vulnerable persons (children, incapacitated adults), confidentiality of data collected, compensation for damage incurred during the research. This draft protocol is largely inspired by the 1990 Recommendation R (90) 3 on medical research on the human being which, considering the date of its adoption, contains principles which are still valid.

3. Organ and tissue transplantation

84. Successful surgical transplantation of certain organs from one human being to another has become possible. The most important surgical difficulties were surmounted, and the development of effective immunosuppressive measures, which are needed for post-operative success, is well advanced. However, transplantation of organs from one human being to another raises a number of legal, ethical and social issues. 4/ In other words, it may be said that there are many human rights issues involved, both from the perspective of organ donors and of recipients.

85. The Governments of Canada, Cyprus, Finland, Monaco, Paraguay, the Russian Federation and Sweden stated that tissue and organ transplantation were regulated by relevant legislation. Some of those Governments described or sent excerpts of their legislation relating to the issue.

86. The Government of Canada stated:

> "One human rights issue that arises regarding organ and tissue transplantation is whether organs are allocated in a fair manner, without discrimination on the basis of sex, race or other irrelevant personal characteristics. For the most part federal, provincial and territorial legislation prohibits discrimination on the basis of age, disability, marital or family status, sex or race in the provision of services and facilities, so that protection is provided against discrimination in the allocation of transplants."

87. The Government of Finland has pointed out:

> "According to the Act on the removal of human organs and tissues for medical use, human organs and tissues may be removed for the purposes of the treatment of another person's disease or injury, preparing a medicine or medical research. According to the Act, organs and tissues may be removed for the purpose of the treatment of another person's disease or injury with the permission of the National Board of Medicolegal Affairs from a person wh has reached the age of 18 and has given a written consent to this."

88. Intelligent, informed and truly voluntary consent for organ transplants has been emphasized as being of paramount importance by the Governments of Canada, Finland, Monaco, the Russian Federation and Sweden. Attention has been drawn to the fact that, before giving his consent, the potential donor must be fully informed by a physician as to the nature of the operation and its consequences, and the risks involved.

89. The Government of Canada stated that:

> "Each provincial and territorial jurisdiction has human tissue legislation. In regard to cadaveric donation, for the most part the donor must have consented as an adult before death, or his or her family must have consented after death. There are only a few situations where organs can be taken on the basis of presumed consent. For example, under the Manitoba Human Tissue Act, eye tissue and pituitary glands may be taken in examinations after death unless there is reason to believe that the deceased (when alive) or a designated family member would have objected.
>
> "In regard to living donations, for the most part in Canada the donor must be mentally competent and have attained the age of majority. In a few jurisdictions there are additional restrictions, e.g., in Newfoundland, where a transplant may be performed only if it is reasonable, taking into account the health of the donor and all the circumstances of the case, and in Quebec, where a donation may not be repeated if it involves a risk to health. There are also certain exceptions to the requirement that the donor must have attained the age of majority, e.g., in Quebec 14-year olds may make donations, in Ontario 16-year olds may do so, and in Manitoba 16-year olds may make donations for family members with the concurrence of a parent or guardian.

"Most jurisdictions expressly prohibit commerce in organs in their human tissue donation legislation, with several exceptions made for blood donations."

90. The Government of Finland pointed out:

"Where a person aged under 18 is concerned, only regenerative tissue may be removed from his body for a special reason with the consent of the person having his custody or his guardian and with the permission of the National Board of Medicolegal Affairs. In this case the donor's opinion of the operation shall be assessed if it is possible with regard to his age and level of development, and the operation must not be carried out if the person opposes it. Consent can be cancelled at any time before the operation. Legislation also limits the removal of organs and tissues from a dead person's body."

91. In Paraguay, the Health Code sets out the following provision concerning consent:

"Article 276 stipulates that for the use of organs, tissues or parts thereof from live human beings or corpses for the purposes set out in the previous article, the donor's wish must have been expressed in writing without coercion, or the written consent of his heirs must have been given."

92. It is generally agreed that a person has the right to control the disposition of his body after death and that the characteristics of consent should be the same as those for consent to be a donor while alive. It is also generally felt that if the deceased person has not expressed his wishes, the transplantation can take place with the consent of his next of kin, but in case of conflict between the wishes of the deceased and those of his relatives, the former prevail.

93. The last clause of article 4 of the Constitution of Paraguay stipulates that "The law shall govern the freedom of individuals to dispose of their own bodies, for scientific or medical purposes only". Article 275 of the Health Code provides that the Health Ministry shall regulate and monitor the obtaining, conservation, use and supply of organs, tissues or parts thereof from live human beings or corpses for therapeutic, research or teaching purposes.

94. Pursuant to the legislation of a number of States, a transplant cannot be performed until the donor can be said to be dead in an accepted sense, given the fact that death takes place in stages. As a result, there is a trend towards recognizing the cessation of cerebral function, sometimes referred to as "brain death" and "irreversible coma", as a new definition of death.

95. In May 1991, the forty-fourth World Health Assembly endorsed the Guiding Principles on Human Organ Transplantation. As pointed out in the preamble, the Guiding Principles were intended to provide an orderly, ethical and acceptable framework for regulating the acquisition and transplantation of human organs for therapeutic purposes.

96. The term "human organ" is understood to include organs and tissues but does not extend to reproductive tissues, namely ova, sperm, ovaries, testicles or embryos, nor is it intended to deal with blood or blood constituents for transfusion purposes. The Guiding Principles prohibit giving and receiving money, as well as any other commercial dealing in this field, but do not affect payment of expenditures incurred in organ recovery, preservation and supply. Of particular concern to WHO is the protection of minors and other vulnerable persons from coercion and improper inducement to donate organs.

97. WHO stated that the Guiding Principles themselves had been extensively used at the national level in the formulation and drafting of legislation of guidelines. For example, the December 1992 Law of the Russian Federation on the transplantation of human organs and/or tissues (which came into force on 1 May 1993) includes a preamble indicating that the Law is "based on the contemporary achievements of science and medical practice and [takes] into account the recommendations of the World Health Organization".

98. The Council of Europe stated that it had given priority to the preparation of a protocol on organ transplantation in order to prevent abuses which were all the more serious since they concern the integrity of the human being. The main provisions are divided into three parts: organ removal from deceased donors, organ removal from living donors and the common provisions to these two types of removal.

99. It has to be stressed that the draft protocol defines the term "organ" in a very broad sense, so as to apply to all parts of the human body, including tissues and cells. However, it excludes from its scope blood, blood constituents, ova, sperm and embryonic and foetal organs. The protocol aims at preventing trafficking and therefore transplantations shall only be performed in establishments which are officially accredited or recognized by competent authorities. Moreover, doctors carrying out transplantations will have to check that the organs have been supplied by such establishments and that all risks of disease transmission have been identified and eliminated. Both these provisions aim at preventing trafficking and ensuring the quality of organs.

100. Principle 15 of the Guiding Principles prepared by CMA provides that:

> "Physicians must safeguard the rights and interests of potential donors and recipients by observing the internationally accepted rules and procedures for transplantation."

In the commentary to this principle, it is stated:

> "In some countries potential live donors are at particular risk from financial or other inducements to donate their organs. Physicians involved in transplantation have an obligation to explain fully to potential donors the risks associated with removal of organs or tissues and the possible consequences to health, and to ensure that the decision to donate has been entirely voluntary, i.e. it has not been influenced by coercion, financial inducement, or undue pressure from other sources,

such as by the family of a potential recipient. The selection of recipients for available organs should be made on the basis of their medical suitability for the procedure."

4. Family planning: artificial insemination and abortion

101. The concept of the right to decide freely and responsibly on the number and spacing of children was declared a "human right", first in article 16 of the Proclamation of Tehran (1968), followed by the 1969 Declaration on Social Progress and Development (arts. 4 and 22) and other declaratory instruments. It appears that this right has now become part of international treaty law through article 16 (1) (e) of the Convention on the Elimination of All Forms of Discrimination against Women. It seeks to ensure that men and women enjoy "the same rights to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights".

102. In that respect the Government of Norway stated:

"The knowledge gained from the potential in new diagnostic methods makes it necessary to define the line between foetal defects that would permit termination of a pregnancy once the 12-week limit had expired, and those that would not. This must be assessed in relation to the situation the woman finds herself in, or will find herself in. Consideration of legal protection for the foetus must be weighed against consideration of the consequences for the mother and the family if the pregnancy is allowed to go full-term. This assessment must also include consideration of the responsibility that society should be able to force expectant parents to accept the situation when the parents themselves do not feel able to bear it. The guidelines society must follow in these difficult evaluations must be based on a system of values that a great majority in society can follow and accept the consequences of."

103. The Government of Norway felt that the status of an embryo was a question to which there was no clear and unambiguous answer. In this view, there is a significant biological difference between an embryo and a fully developed foetus, and the gradual growth of an embryo must have consequences for the evaluation of the status of the foetus. The same criteria is used in current legislation concerning termination of pregnancy - namely that the legal rights of the foetus increased in line with its biological development, in other words with the duration of the pregnancy.

104. The Government of Paraguay pointed out that its Ministry of Public Health and Social Welfare organized family planning programmes on the basis of relevant legislation. These are mainly aimed at controlling the birth rate of the low-income population, and for this purpose officials are trained to give talks on the subject in communities in the interior of the country. The lack of human and financial resources prevents reaching more remote areas.

105. The Penal Code of Paraguay, in chapter XIII concerning offences against the life, physical integrity and health of individuals, contains legislation on abortion or the destruction of foetuses. Article 349 stipulates that a woman who provokes her own abortion, by any means used either by herself or by

a third person with her consent, shall be liable to imprisonment for 15 to 30 months. If she acted with the intention of safeguarding her good name she shall be liable to imprisonment for 6 to 12 months. The Penal Code similarly provides for more severe penalties for cases resulting in the woman's death, of for the use of more severe means than those to which she had consented.

106. There is also exemption from penalties for persons who can provide proof of having acted with the aim of saving the life of a woman endangered by her pregnancy or childbirth. The legislation of Paraguay also includes Decree No. 2,448 of 10 December 1937, which provides for the prevention and punishment of criminal abortion and encourages the bearing of children.

107. The European Commission of Human Rights sent some of the Commission case law which might be relevant to this issue. For instance, in the case of Rose Marie Bruggeman and Adelheid Sheuten v. the Federal Republic of Germany, the question was raised whether provoked abortion amounted to a violation of the right to respect for private life embodied in article 8 of the European Commission. The European Commission examined whether the regulation of provoked abortion was justified as an intervention in private and concluded that "pregnancy can not be said to pertain uniquely to the sphere of private life. Whenever a woman is pregnant her private life becomes closely connected with the developing foetus". The European Commission also looked at the national legislations and it stated that provoked abortion was generally allowed in most of the member countries within a certain time period. Against this background the European Commission found that no violation of private life in the sense of the Convention had taken place. 5/

108. In one of its reports WHO pointed out that according to the legislation of a number of countries, induced abortion may be performed for one or more of the following indications:

(a) To safeguard the physical or mental health of the mother;

(b) Where a pregnancy results from rape or incest, or occurs in a female who is below a specified age;

(c) Where the mother has had rubella at a critical stage of gestation with a resultant risk of congenital imperfections of the child, or has run some other risk, such as from drugs or ionizing radiation, of damage to foetal development;

(d) Where Down's syndrome or other chromosomal anomaly has been diagnosed by amniocentesis, or by other means;

(e) Where parents are mentally defective and considered to be incapable of caring adequately for a child.

109. Apart from these indications based on medical, eugenic or medico-social considerations, some legal texts provide for the authorization of abortion on socio-economic or economic grounds. The extreme in the liberal attitude is provided by the so-called "abortion on demand" or "abortion on request". There is universal recognition that induced abortion is not to be considered a preferred method of family planning. 6/

110. Legal and other problems arising from the development of artificial insemination were considered in the report of the Secretary-General mentioned above. 7/ This report pointed out that since the Second World War artificial insemination had come to the attention of legislators, the public, the courts, and social scientists and religious leaders. Its practice was largely confined to the technologically more highly developed countries, although even in those countries only rough and inconsistent estimates of the incidence of the practice were available.

111. That report stated that only a few jurisdictions had legislated on the subject. The medical profession itself had generally regulated the practice in conformity with the applicable codes of medical ethics and general legal principles. One of the legal problems involved concerns the issue of consent. Assuming consent by the woman to be inseminated, the question of the consent of her husband remains. In practice, most medical practitioners will not perform the procedure without the consent of both spouses, and generally obtain such consent in writing - for evidentiary reasons. The written consent of the donor for his semen to be used for artificial insemination is also generally obtained. 8/

112. Only a few replies received mentioned the issue. The Government of Germany pointed out that the Protection of Embryos Act which entered into force on 1 January 1991 is aimed at preventing possible abuses in the use of new reproduction techniques. In its opinion, the increasing significance of in vitro fertilization as well as the use of genetic engineering methods on human beings confronted the legislature with the task of setting boundaries for that which is legally admissible and, at the same time, establishing a balance between the conflicting constitutional values of life and human dignity, on the one hand, and the freedom of research, on the other. Against this background, prohibitions liable to criminal prosecution were stipulated where they seemed indispensable for the protection of especially important legal interests, for example in the event of specific cases of misuse of modern reproductive medicine, misuse of human embryos, artificial modification of human cells, cloning, as well as chimera and hybrid creation.

113. Chapter 4 of Danish Law N 503 of 24 June 1992 provides, inter alia:

> "Subsection 3. The fertilized human eggs must only be kept alive outside the womb of a woman for 14 days from the time of fertilization, the duration of deep freezing of the fertilized eggs not included.
>
> Subsection 4. Fertilized human eggs that have been the subject of biomedical research according to subsection 1, must not be inserted in a woman's womb, unless this can happen without any risk of transferring genetic diseases, defects, malformations, etc.
>
> Subsection 5. Donation of fertilized human eggs are not permitted.
>
> Subsection 6. The Minister of Health is authorized to lay down rules on freezing and donation of human eggs."

114. The Vatican Congregation for the Doctrine of the Faith condemned in vitro fertilization along with all other "artificial" forms of procreation as

threats to the sanctity of the conjugal act, to the family, and to human dignity. In addition, it argued that any interference whatsoever with what it regards as natural forms of procreation would lead humanity to a condition of moral numbness.

115. Several complaints have been lodged with the European Commission of Human Rights. In one case, the applicant was a Dutch citizen. In 1985 he and his then wife met Ms. T. and Ms. J., a lesbian couple. After some discussions the applicant agreed to donate sperm to Ms. T. In November 1986 Ms. T. was artificially inseminated and on 30 July 1987 a daughter was born. Ms. T. is the child's guardian by law. By judicial order of 27 August 1987, the District Court judge (Kantonrechter) of Utrecht appointed Ms. J. as co-guardian. During Ms. T.'s pregnancy and after the child's birth the applicant visited Ms. T. and Ms. J. regularly and between September 1987 and April 1988 baby-sat on Monday afternoons.

116. In the beginning of 1988 the applicant informed Ms. T. and Ms. J., referring to alleged previous agreements on the raising of the child, that he wished to establish certain visiting arrangements, inter alia that the child would spend one week-end per month with him. Ms. T. and Ms. J. denied that any previous agreements in this respect had been made in the past and in May 1988 broke off all contacts with the applicant and refused further contacts between the applicant and the child. The Juvenile Court judge refused the applicant's request for access.

117. The Commission considered that the situation in which a person donates sperm only to enable a woman to become pregnant through artificial insemination did not of itself give the donor a right to respect for family life with the child. It followed also that this complaint was manifestly ill-founded and must be rejected. 9/

118. This and other cases show that while many of the legal problems posed in connection with artificial insemination arise only in occasional cases, one issue affects every birth resulting from this means: the legal status of the offspring and the sperm donor. This question has not been definitely resolved by application of conventional rules of law and remains the subject of discussion by jurists.

5. Developments in biotechnology

119. The Government of Norway stated:

> "Possibilities and challenges will arise from modern biotechnology and gene technology, not only for society as a whole but also for each individual. Modern biotechnology will continue to give rise to new diagnostic methods, pharmaceuticals, vaccines, and other vital forms of treatments. Gene technology is fast becoming common within virtually every field of biological and medical research. It already plays an important part in the research into cardiovascular diseases, cancer and other common diseases. The widest definition of biotechnology encompasses almost all modern medical diagnostics and treatment ... At a more general level, however, modern human biotechnology seeks to discover

possible treatments for serious diseases. Today, we can barely begin to imagine the extent of these treatments and the considerable consequences they may have for future generations."

120. The Government of Sudan pointed out:

"The Sudan has begun to introduce modern biotechnology in important fields such as biological fermentation and fertilization and textile agriculture in order to increase productivity. It is also still using traditional techniques to improve seeds and breeds and is preparing to introduce genetic engineering technologies in cooperation with regional and international centres and in accordance with the provisions of joint scientific protocols and agreements. The National Centre for Research has become the focal point for biotechnology and genetic engineering in the Sudan and a national committee has been established to coordinate between the relevant institutes and centres in the country."

121. In the view of the Government of Norway, planned genetic improvement in human beings is unacceptable at any level, with the exception of treatment of diseases. The Government is against the use of gene technology or any other methods which may be employed to "improve" future generations.

122. CIOMS pointed out that the ethical and human-values implications of research in human genetics, and particularly those of mapping and sequencing the human genome, were discussed at the XXIVth CIOMS Conference, held in Tokyo and Inuyama City, Japan, in July 1990. At its final session, the Conference agreed on a statement: The Declaration of Inuyama, on human genome mapping, genetic screening and gene therapy, which epitomizes the issues and the consensus of the Conference.

123. In the view of the Conference, the mapping of the human genome will greatly expand the scope of genetic screening and diagnostic tests, and it is in this regard that the welfare of those who are tested must be safeguarded. Test results must be protected against unconsented disclosure, confidentiality assured at all costs, and adequate counselling provided. Genetic researchers and therapists have a responsibility to ensure that the techniques they develop are used ethically. By insisting on truly voluntary programmes designed to benefit directly those involved they can ensure that no precedents are set for eugenic programmes or other misuse of the techniques by the State or by private parties. One means of ensuring the setting and observance of ethical standards is continuous multidisciplinary and transcultural dialogue.

C. Machinery for effective promotion of ethical standards

124. Methods which have been adopted or proposed for the protection of human rights on the national level against threats posed by recent scientific and technological developments relating to the issues dealt with in the present report was described in studies of protection of the human personality and its physical and intellectual integrity in the light of advances in biology (E/CN.4/1172), medicine (E/CN.4/1172/Add.1) and biochemistry (E/CN.4/1172/Add.2).

125. The methods on the national level analysed in those reports included, as appropriate: legislation; administrative regulations and licensing of devices; official guidelines; special governmental machinery; codes of ethics; science policies including suitable policies governing the introduction of new technologies; economic policies; suitable training programmes; safety inspection services; and safety testing of new equipment. To some extent constitutional provisions have been found applicable. There have also been a number of judicial decisions on the protection of human rights against threats posed by recent scientific and technological developments. In some instances, threats posed to rights by certain devices may be countered by appropriate technical procedures or by other technological devices.

126. In addition, in one of those reports the opinions were also expressed that national mechanisms were necessary for technological assessment - including the assessment of possible side-effects and long-range effects - whether the time was right for particular innovations and whether their advantages outweighed for the society the discernible disadvantages. 10/

127. As can be seen from the replies analysed above, many of the ethical standards which have a human rights component are enforced through the operation of the law, although the extent to which this occurs varies considerably between States and, more specifically, between systems of law. The task of implementing ethical standards requires the elaboration of the relevant legislation. Working out pertinent recommendations for Government in this field usually falls on special bodies.

128. In the information from the Government of Canada, it is stated:

> "The Continuing Committee of Officials on Human Rights maintains consultation and collaboration among governments in Canada with respect to the domestic implementation of international human rights instruments. It also serves as a consultation mechanism on other domestic or international human rights questions related to human rights instruments. At the 1988 Federal/Provincial/Territorial Ministerial Conference on Human Rights, ministers responsible for human rights identified issues relating to the human rights implications of medical research involving human beings, organ and tissue transplantation, AIDS and drug testing, and instructed officials of the Continuing Committee on Human Rights to prepare reports and keep apprised of developments regarding these matters. These reports have been prepared, and will be updated as appropriate. They have not yet been considered by ministers."

129. The Government of Canada also pointed out that:

> "The primary role of the Medical Research Council is to fund research and to establish the basic ethical guidelines that must be met for it to be acceptable. In 1990 the National Council on Bioethics in Human Research was established, with a mandate to maintain high ethical standards of biomedical and health related research involving human beings in Canada. It works towards these standards by definition of appropriate guidelines and by providing consultation and advice to investigators, research granting agencies and institutional research ethics boards. The National Council on Bioethics in Human Research is an independent organization

that reports to the Royal College of Physicians and Surgeons, the Medical Research Council and Health Canada, and receives funding from Health Canada."

130. In 1989 the Royal Commission on New Reproductive Technologies was created by the Government of Canada with a mandate to inquire into and report on developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied. In 1993, after wide consultations, the Royal Commission on New Reproductive Technologies published its report, entitled "Proceed With Care". The Commission identified a number of problems sometimes encountered in reproductive technology, including the following:

(a) Use of sperm from donors who have not been tested for HIV;

(b) Lack of records kept regarding the parentage of children conceived by means of reproductive technology;

(c) Insufficient prevention of infertility;

(d) Lack of respect for women's reproductive choices;

(e) Discriminatory practices regarding access to reproductive technology;

(f) Offering of technology of questionable utility; and

(g) Use of technology inconsistent with Canadian values.

131. The Royal Commission on Reproductive Technologies made two main recommendations for reform in its report "Proceed With Care". First, the Royal Commission recommended the enactment of legislation to prohibit, with criminal sanctions, several aspects of new reproductive technologies, such as using embryos in research related to cloning, animal/human hybrids, the fertilization of eggs from female foetuses for implantation, the sale of eggs, sperm, zygotes or foetal tissues, and advertising for, paying for or acting as an intermediary for preconception (surrogacy) arrangements. Second, the Commission recommended the creation of a National Reproductive Technologies Commission to act as a regulating and licensing body in this area.

132. In Denmark, a scientific ethical committee system was created by Law N 503 of 24 June 1992 in order to protect participants in biomedical research projects. The county councils appoint regional scientific ethical committees. A county council can appoint one or more committees within its geographical area. Also, more than one county council can appoint a committee.

133. With reference to the tasks of the committee system, the Government of Denmark stated:

"As a part of their evaluation the committees will have to secure that:

(1) the risks, that might be connected with the implementation of a project, have been meticulously judged and that they not in themselves or in relation to the foreseeable advantages of the project have an unjustifiable magnitude,

(2) the patients or healthy volunteers, participating in the project will be informed in writing and verbally about its content, foreseeable risks and advantages, and that their free and explicit consent will be obtained and given in writing, cf. subsection 3,

(3) information will be given to, and consent obtained from, the closest relatives, guardian or donor in such cases where the study is carried through under circumstances that exclude information and attainment of consent according to point 2,

(4) it is obvious from the information sheets that patients and healthy volunteers or relatives, guardian or donor at any time can retract their consent, and

(5) the project according to its aim and as regards its methodology represents good scientific standards, besides the existence of sufficient reasons for carrying through the project."

134. The Danish Parliament passed Act N 353 of 3 June 1987 on establishment of an Ethical Council and regulation of certain forms of biomedical experiments. According to the Act the Council is established by the Minister of the Interior. The Council should submit recommendations to the Ministry concerning the establishment of statutory rules on the protection of the fertilized human egg, the living embryo and the foetus. It should also submit to the Ministry recommendations concerning the possibility of carrying out genetic treatment of human gametes which are used for fertilization, and of fertilized human eggs, embryos and foetuses, as well as the possibility of using new diagnostic techniques in order to discover congenital defects or diseases in the fertilized human egg, embryo and foetus. In addition, the Council should submit a recommendation concerning the establishment of the rules on the deep-freezing of human gametes intended for fertilization and of fertilized human eggs.

135. According to Cyprus law, the Pancyprian Medical Association is the responsible body for issuing regulations concerning human rights and bioethics. The Association is an observer member of the Standing Committee of the National Medical Association of the European Union. Any legislative measures or decisions taken by the Standing Committee are endorsed by the Pancyprian Medical Association provided these measures are not against Cyprus law. The Association issues regulations concerning artificial insemination, in vitro fertilization, death-related matters - terminal illness, organ transplantation, AIDS, Jehovah's witnesses, etc.

136. In Paraguay, the Health Sciences Research Institute of the National University of Asunción has set up a Research Ethics Committee to ensure that ethical standards in research are observed. In all strictly ethical matters

the Committee is empowered to take binding decisions; the Committee does not, however, have an executive or governing function although the Committee is represented on the governing body. Specifically, it assesses the methodological, ethical and legal aspects of a proposed research project, and weighs risks against benefits.

137. In Sweden, most policy issues are dealt with by commissions appointed by the Government before the Government delivers a bill to Parliament. When the Government has received the proposals from the commission they are sent for views to a number of organizations, authorities, etc. In the last few years, quite a number of commissions have been dealing with different questions of medical ethics.

138. In addition to the system of separate commissions, Sweden has had a National Council of Medical Ethics since 1985. It is an advisory body to the Government, working under the Ministry of Health and Social Affairs. One of its tasks is to shed light on fundamental issues of medical ethics from an overall perspective, to keep abreast of research and act as a link between science, the public and political decision-makers.

139. Here one must observe the difference between, on the one hand, national committees on medical ethics dealing with policy questions, underlying values and ethical principles, etc. and on the other hand research committees dealing with research ethics connected to individual research projects. The National Council of Medical Ethics is a policy-making commission. All these committees are - or have been - financed by the Government. The committees get their terms of reference from the Government and are appointed by the Government. A committee might be restricted to a group of experts but may also include members of Parliament. A committee usually includes 10-20 members.

140. The Portuguese Government pointed out that in accordance with law 14/90 of 9 June 1990 the National Council of Ethics for the Life Sciences was created.

141. The Government of the Russian Federation mentioned the important role played by the Academy of Sciences and its institutes in cooperation with the relevant governmental agencies in the field of bioethics. The Russian National Committee on Bioethics was established in 1992. This public organization composed of scientists in the fields of biology, medicine and the human sciences prepared and published recommendations concerning the necessity of strict ethical control of medical experiments.

142. In order to protect its people from the hazards to which they might be exposed as a result of research activity, the circulation of substances, the importation of live specimens and the introduction of modern biological techniques, the Sudan has established numerous regulatory and monitoring institutions such as:

(a) The Medical Council, which is responsible for professional ethics and the licensing of medical and pharmaceutical research;

(b) The Pesticides and Poisons Committee, which supervises the manufacture, circulation, distribution and processing of pesticides and poisons used for purposes of research and other applications;

(c) The Agricultural Quarantine Division of the Customs Department, which controls and regulates the entry of live specimens of plants, animals and microorganisms.

143. The Government of Namibia pointed out that human rights education, especially relating to life sciences, has become an integral part of education for all. The Life Skills curriculum is based on the concept of life-centred education, the philosophy of which is that education should embrace the full range of life experiences and not merely be limited to the acquisition of academic and pre-vocational skills. It is a total or holistic approach designed to prepare students effectively for the various roles which they will both now and in the future be called upon to play in their day-to-day functioning inside and outside the classroom. In the spirit of its "real life"-oriented approach, it makes full use of teacher, student and community input to achieve its learning objectives, which take the diverse needs of urban and rural students, slow learners and mildly retarded students into account.

144. The Holy See pointed out that given its nature, it acts in a specific manner in order to develop life sciences respecting human rights primarily by the way of formation of conscience. The Popes have promulgated official doctrinal documents such as the encyclicals "Humanae vitae" (1968) and "Veritatis splendor" (1993), as well as official communications addressed to scientists, doctors and specialized organizations. A working group on bioethics has been established within the State Secretariat. It is composed of experts in the field of medicine, genetics, ethics and law, and plays an advisory role especially regarding initiatives at the international level.

145. UNESCO pointed out that the Director-General of UNESCO took the initiative of creating an International Bioethics Committee. This Committee, whose 50 members have been designated for four years, includes the world's most renowned specialists in the field of biology, genetics, medicine, law, philosophy and the human sciences. One of its main tasks is to clarify the proposed principles that will respond to the main ethical preoccupations resulting from progress in the life sciences. The International Bioethics Committee will ground its preparation of this international instrument on the universal approach to human rights. Moreover, the IBC has stressed its will to adopt a constructive approach to bioethical questions in an open and pragmatic way. It will seek above all to assess the conditions in which progress in genetics can contribute to world stability as well as to combating injustice, poverty, handicaps and illness.

146. On the basis of the report prepared by Mrs. Noëlle Lenoir, the Chairman of IBC, and of the preliminary work done by the International Bioethics Committee, the Director-General submitted to the twenty-seventh session of the General Conference (October-November 1993) a study concerning the possibility of drawing up an international instrument for the protection of the human

genome. The General Conference of UNESCO adopted resolution 27 C/5.15 by which it invited the Director-General to continue in 1994-1995 the preparation of such an instrument.

147. The Council of Europe pointed out that its Committee of Ministers has entrusted the Steering Committee on Bioethics with the preparation of a third protocol on the protection of the human embryo and foetus. The Council of Europe has been very active in the field of biomedicine for the last 20 years. In particular, the Parliamentary Assembly and the Committee of Ministers of the Council of Europe adopted a number of resolutions and recommendations on bioethical matters. Both organs supervise the execution of their decisions.

III. CONCLUSIONS AND RECOMMENDATIONS

148. The analysis of replies received shows that developments in biology and medicine have a direct impact on human rights, in particular on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

149. It is obvious that a number of issues considered in this document are of concern to both developed and developing countries. However, transplantation of organs, artificial insemination and other pertinent advanced technologies are restricted to developed countries, and even within them (as is the case of organ transplantation) to a limited number of persons.

150. The fundamental questions of how far do States and individuals benefit from advances in medicine and biology are only partly answered in the present document which dealt with the present and potential problems posed to human rights by developments in biology and medicine.

151. On the other hand, legislation re-enforcing certain ethical principles has been introduced by a number of States which also have established relevant machinery for the implementation of legal rules and giving effect to ethical standards.

152. It may also be stated that the rapid development of science and its technological applications which have taken place in recent decades have not been accompanied by an appropriately urgent, profound and continuous consideration of their implications for human rights. It has been asserted that such consideration has become all the more urgent since new scientific discoveries now pass more rapidly than ever into practical application, and that they have implications for human rights is often foreseen.

153. Nevertheless, there is a growing conviction that there is a need for continuing technology assessment on the national level in order to assess possible side-effects and long-range effects of innovations and to establish whether their advantages outweigh the discernible disadvantages, and for control over innovations with harmful potentialities.

154. There is a general recognition of the need for international cooperation in order to ensure that mankind as a whole benefits from the life sciences and to prevent them from being used for any purpose other than the good of mankind. There is also a recognition of the need to develop a life sciences

ethic at the national and international levels. The adoption of relevant national legislation is an encouraging development. The elaboration of pertinent instruments by the Council of Europe and UNESCO is also a significant step towards setting international standards in the field.

155. The concepts of freedom for the individual and personal integrity are central to the tradition of human rights. Individual codes of ethics should be influenced by the ethical codes of society, and vice versa. This makes it necessary to find a balance between the rights of the individual and the boundaries society should impose on this right, based on the fundamental values of the society. The ethics of this area must be reflected in both the legislation, as well as in the boundaries imposed by society on the development of the measures.

156. The Government of Norway considers that, for obvious reasons, future research into, and the use of, biotechnology must be based on ethical guidelines. The aims, means, consequences and standards involved must be ethically assessed and views must be based on values which are acceptable to the majority of the population. These values must take into account the long-term possibilities and consequences involved. The central and overriding principles governing developments in this area must be a respect for human dignity, human rights and the principle of solidarity.

157. The Norwegian Government wishes to establish the following principles, which may be of interest for human rights organs:

> "Modern medical expertise and technology must be used in the best interests of mankind within the ethical boundaries established by society.
>
> "This ethical framework must be built on overriding principles of respect for human dignity and human rights and the principle of solidarity.
>
> "The rights of all individuals shall be secured for the protection of the individual against undesirable consequences.
>
> "With the exception of the treatment of diseases, planned genetic improvement in human beings is unacceptable at any level.
>
> "New forms of prenatal diagnosis and genetic screening should only be permitted within the public health sector.
>
> "The Government aims for a society where everyone plays a role and is fully valued.
>
> "Openness and access for the public to all information should ensure confidence that biotechnological and gene technological research within medicine will benefit society."

158. CIOMS is of a view that bioethics in the health sector should be guided by generally accepted principles, and in particular the following:

> "an adequate level of health care should be recognized as a universal and fundamental human right;
>
> "equity should be considered a foundational principle for health policy, and such policy should be based on the Alma-Ata principle of Health for All;
>
> "health services should be effective, efficient, accessible, affordable, compassionate, and socially acceptable; and
>
> "mechanisms should be developed to ensure that communities are enabled to meaningfully participate in the development of health policy and services, and communities and individuals should be involved in determining the nature and quality of health care."

159. In the view of CIOMS, bioethics seeks to define ways and means to ensure that health promotion and health care are in harmony with the protection of life and human values, particularly human dignity; the principles of bioethics entail concrete obligations on the part of international agencies, Governments, health care providers, professional associations and society at large, as well as individuals and specific groups of the population. Bioethics recognizes that ethical norms and values differ significantly from culture to culture. At the same time, bioethics must seek to identify certain fundamental ethical principles that promote human rights and welfare and that can be applied across all cultures.

160. CIOMS considers that efforts should be made to promote and strengthen the continuing development of national and international capacities for ethical analysis of current and emerging changes in health care affecting individuals and populations. Efforts should also be made to promote the further development of national and international protection of the most vulnerable; this will involve organizing and assisting individuals, groups, communities and Governments at all levels to enhance their understanding of the causes and the circumstances contributing to different forms of vulnerability and their capacities for corrective action, and fostering a global sense of constructive interdependence among all countries.

161. In the light of the fact that bioethics has developed primarily, but not exclusively, in the most developed countries, there is a pressing need for the elucidation and universal adoption of basic bioethical principles, in a manner that acknowledges the world's diverse moral and cultural perspectives, priorities and values. A significant step towards this objective should be the setting up of bilateral and multilateral links, such as technical cooperation, exchanges and information, among institutions and professional societies dealing with bioethics in industrialized countries and their counterparts in developing countries; such associations would be mutually beneficial.

162. The positive uses of modern sciences and technologies in the field of biology and medicine for the promotion of human rights are potentially vast,

but their exploitation depends upon the laying down of appropriate science policies on the national level and the creation of machinery to carry out those policies.

163. Especially within developing societies, where the need for surveillance or regulatory mechanisms is most urgent and acute, there is a dearth or a total absence of such mechanisms. Much thought needs to be given to this problem with a degree of special urgency, for as long as such structures are not in place every advantage will be taken of their absence to introduce technologies in the interests of private profit which impede the flow of human rights benefits to the bulk of the populations of developing nations.

Notes

1/ Tom J. Farer, "Human Rights and Scientific and Technological Progress: A Western Perspective", in Human Rights and Scientific and Technological Development, C.G. Weeramantry (ed.), United Nations University Press, Tokyo, 1990, p. 78.

2/ See report of the Secretary-General entitled "The balance which should be established between scientific and technological progress and the intellectual, spiritual, cultural and moral advancement of humanity" (E/CN.4/1199 and Add.1) and Human Rights and Scientific and Technological Developments, op. cit.

3/ See Human Rights and Scientific and Technological Developments, Department of Public Information, United Nations, New York, 1982, p. 71.

4/ See document E/CN.4/1172, paragraphs 113-139.

5/ Application N 6959/75.

6/ See document E/CN.4/1173, chapter 3.

7/ See document E/CN.4/1172, paragraphs 18-111.

8/ Ibid., paragraph 75.

9/ Application N 16944/90.

10/ See document E/CN.4/1199/Add.1, paras. 170 and 172.

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